

IM2003

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service under 37 CFR §1.8 on the date indicated below and addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

Cygnus Docket 0251.02  
Serial No. 10/643,631  
PATENT

Barbara Nolan

Printed Name

Barbara Nolan  
Signature

Oct. 15, 2003  
Date of Deposit

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Janet A. TAMADA, et al

Examiner:  
unassigned

Serial Number: 10/643,631

Filed: August 18, 2003

Group Art Unit:  
unassigned

For: COMPOSITIONS AND METHODS FOR  
ENHANCEMENT OF TRANSDERMAL  
ANALYTE FLUX

**TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, a Form PTO-1449, and copies of the required cited references. It is believed that no fee is due.

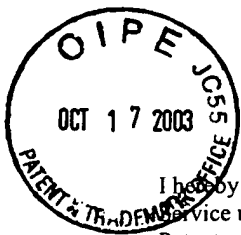
The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 03-4058. However, this is not authorization to pay the Issue Fee.

Respectfully submitted,  
Cygnus, Inc.

Dated: 15 Oct 2003

By: Gary R. Fabian  
Gary R. Fabian  
Agent for Applicants  
Registration No. 33,875

Cygnus, Inc.  
400 Penobscot Drive  
Redwood City, CA 94063  
Phone (650) 369-4300  
Fax (650) 599-3913



CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service under 37 CFR §1.8 on the date indicated below and addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

Cygnus Docket 0251.02  
Serial No. 10/643,631  
PATENT

Barbara Nolan

Printed Name

*Barbara Nolan*

Signature

*Oct. 15, 2003*

Date of Deposit

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Janet A. TAMADA, et al

Examiner:  
unassigned

Serial Number: 10/643,631

Filed: August 18, 2003

Group Art Unit:  
unassigned

For: COMPOSITIONS AND METHODS FOR  
ENHANCEMENT OF TRANSDERMAL  
ANALYTE FLUX

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The information listed below may be material to the examination of the above-identified application. A completed Form PTO-1449 listing the references accompanies this paper. Copies of the references that are being newly submitted are included.

Because this application was filed after 30 June 2003, copies of cited U.S. Patent and U.S. Patent Application publications have not been submitted pursuant to the waiver described in pre-OG Notice "Information Disclosure Statements may be filed without copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003".

Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record in the present application.



This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

*Gary R. Fabian*

Gary R. Fabian  
Agent for Applicants  
Registration No. 33,875

Date: 15 Oct 2003

Cygnus, Inc.  
400 Penobscot Drive  
Redwood City, CA 94063  
Phone 650-369-4300  
Fax 650-599-3913



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 1 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

U.S. PATENT DOCUMENTS

Exam Init.	Ref. Desig.	Document No.	Date	Name	Class	Sub- Class	Filing Date
	AA-1	4,020,830	May 3, 1977	Johnson et al.			
	AA-2	4,200,098	April 29, 1980	Ayer et al.			
	AA-3	4,406,827	September 27, 1983	Carim			
	AA-4	4,474,570	October 2, 1984	Ariura et al.			
	AA-5	4,492,622	January 8, 1985	Kuypers			
	AA-6	4,684,558	August 4, 1987	Keusch et al.			
	AA-7	4,702,732	October 27, 1987	Powers et al.			
	AA-8	4,706,680	November 17, 1987	Keusch et al.			
	AA-9	4,722,726	February 2, 1988	Sanderson et al.			
	AA-10	4,722,761	February 2, 1988	Cartmell et al.			

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 2 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

	AA-11	4,731,049	March 15, 1988	Parsi			
	AA-12	4,764,164	August 16, 1988	Sasaki			
	AA-13	4,777,954	October 18, 1988	Keusch et al.			
	AA-14	4,968,297	November 6, 1990	Jacobsen et al.			
	AA-15	4,989,607	February 5, 1991	Keusch et al.			
	AA-16	5,036,861	August 6, 1991	Sembrowich et al.			
	AA-17	5,037,380	August 6, 1991	Jacobsen et al.			
	AA-18	5,057,072	October 15, 1991	Phipps			
	AA-19	5,069,908	October 3, 1991	Henley			
	AA-20	5,076,273	December 31, 1991	Schoendorfer et al.			
	AA-21	5,134,057	July 28, 1992	Kuypers et al.			
	AA-22	5,140,985	August 25, 1992	Schroeder et al.			
	AA-23	5,143,071	September 1, 1992	Keusch et al.			

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 3 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

	AA-24	5,152,758	October 6, 1992	Kaetsu et al.			
	AA-25	5,205,297	April 27, 1993	Montecalvo et al.			
	AA-26	5,279,543	January 18, 1994	Glikfeld et al.			
	AA-27	5,291,887	March 8, 1994	Stanley et al.			
	AA-28	5,330,527	April 26, 1993	Montecalvo et al.			
	AA-29	5,340,722	August 23, 1994	Wolfbeis et al.			
	AA-30	5,354,790	October 11, 1994	Keusch et al.			
	AA-31	5,362,307	November 8, 1994	Guy et al.			
	AA-32	5,362,308	November 8, 1994	Chen et al.			
	AA-33	5,405,366	April 11, 1995	Fox et al.			
	AA-34	5,428,123	June 27, 1995	Ward et al.			
	AA-35	5,636,632	June 10, 1997	Bommannan et al.			
	AA-36	5,651,869	July 29, 1997	Yoshioka et al.			

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 4 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

	AA-37	5,730,714	March 24, 1998	Guy et al.			
	AA-38	5,735,273	April 7, 1998	Kurnik et al.			
	AA-39	5,771,890	June 30, 1998	Tamada			
	AA-40	5,786,216	July 28, 1998	Dionne et al.			
	AA-41	5,823,957	October 20, 1998	Faupel et al.			
	AA-42	5,827,183	October 27, 1998	Kurnik et al.			
	AA-43	5,954,685	September 21, 1999	Tierney			
	AA-44	5,965,380	October 12, 1999	Heller et al.			
	AA-45	5,989,409	November 23, 1999	Kurnik et al.			
	AA-46	6,023,629	February 8, 2000	Tamada			
	AA-47	6,083,710	July 4, 2000	Heller et al.			
	AA-48	6,121,009	September 19, 2000	Heller et al.			
	AA-49	6,139,718	October 31, 2000	Kurnik et al.			

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 5 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

	AA-50	6,162,611	December 19, 2000	Heller et al.			
	AA-51	6,299,578	October 9, 2001	Kurnik et al.			
	AA-52	6,393,318	May 21, 2002	Conn et al.			
	AA-53	6,615,078	September 2, 2003	Burson, et al.			

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub-Class	Translation YES NO	
	AB-1	EP 0 304 304	February 22, 1989	EPO				
	AB-2	EP 0 539 625	May 5, 1993	EPO				
	AB-3	EP 0 942 278	September 15, 1999	EPO				
	AB-4	WO 91/12772	September 5, 1991	PCT				
	AB-5	WO 92/07619	May 14, 1992	PCT				
	AB-6	WO 92/10234	June 25, 1992	PCT				
	AB-7	WO 93/10163	May 27, 1993	PCT				

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 6 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

	AB-8	WO 95/02357	January 26, 1995	PCT				
	AB-9	WO 96/00109	January 4, 1996	PCT				
	AB-19	WO 96/00110	January 4, 1996	PCT				
	AB-11	WO 97/02811	January 30, 1997	PCT				
	AB-12	WO 97/10499	March 20, 1997	PCT				
	AB-13	WO 97/24059	July 10, 1997	PCT				
	AB-14	WO 97/38126	October 16, 1997	PCT				
	AB-15	WO 97/42882	November 20, 1997	PCT				
	AB-16	WO 97/42885	November 20, 1997	PCT				
	AB-17	WO 97/42886	November 20, 1997	PCT				
	AB-18	WO 97/42888	November 20, 1997	PCT				
	AB-19	WO 97/43962	November 27, 1997	PCT				
	AB-20	WO 99/58190	November 18, 1999	PCT				

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 7 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
	AC-1	Abstract of JP 56137899, Published 10/28/81
	AC-2	Albin et al., "Theoretical and Experimental Studies of Glucose Sensitive Membranes," <i>Journal of Controlled Release</i> <u>6</u> :267-291 (1987)
	AC-3	Allcock et al., "Activity of Urea Amidohydrolase Immobilized Within Poly[di(methoxyethoxyethoxy)phosphazene] Hydrogels," <i>Biomaterials</i> <u>15</u> (7):502-506 (1994)
	AC-4	Asakura et al., "Immobilization of Glucose Oxidase on Nonwoven Fabrics with Bombyx mori Silk Fibroin Gel," <i>Journal of Applied Chemistry</i> <u>46</u> (1):49-53 (1992)
	AC-5	D'Urso et al., "Poly(ethylene glycol)-Serum Albumin Hydrogel as Matrix for Enzyme Immobilization: Biomedical Applications," <i>Art. Cells. Blood Subs., and Immob. Biotech.</i> <u>23</u> (5):587-595 (1995)
	AC-6	Glikfeld et al., "Noninvasive Sampling of Biological Fluids by Iontophoresis," <i>Pharm. Res. (US)</i> <u>6</u> (11):988-990 (1989)
	AC-7	Heller et al., "Controlled Drug Release by Polymer Dissolution II: Enzyme-mediated Delivery Device," <i>J. Pharmaceut. Sci.</i> <u>68</u> (7):919-921 (1979)
	AC-8	Kalisz, H. M., et al., "Purification of the Glycoprotein Glucose Oxidase From <i>Penicillium amagasakiense</i> by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> <u>521</u> :245-250 (1990)

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Atty Dkt No. 0251.02

COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

FORM PTO-1449 (Modified)  
LIST OF PATENTS AND PUBLICATIONS  
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)  
Sheet 8 of 8

In the Application of TAMADA et al.

Serial No.: 10/643,631

Art Unit: Unassigned

Filed: August 18, 2003

Examiner: Unassigned

Title: COMPOSITION AND METHODS FOR ENHANCMENT OF TRANSDERMAL ANALYTE FLUX

Exam. Init.	Ref. Desig.	Description
	AC-9	Kost et al., "Glucose Sensitibe Membranes Containing Glucose Oxidase: Activity, Swelling, and Permeability Studies," <i>J. Biomed. Materials Res.</i> <u>19</u> (9):1117-1133(1985)
	AC-10	Lesho, et al, "A Photopatterned Glucose Responsive Hydrogel for Use in a Conductimetric Sensor", Materials Research Society Symposium Proceeedings, 1994, Vol. 331, pages 193-198
	AC-11	Meyerhoff et al., "On Line Continuous Monitoring of Subcutaneous Tissue Glucose in Men by Combining Portable Glucosensor with Microdialysis," <i>Diabetologia (Germany)</i> <u>35</u> (11):1087-1092 (1992)
	AC-12	Newman,J.D., et al., "Catalytic Materials, Membranes, and Fabrication Technologies Suitable for the Construction of Amperometric Biosensors," <i>Analytical Chemistry</i> <u>67</u> :4594-4599 (1995)
	AC-13	Tamada et al., "Noninvasive Glucose Monitoring," <i>JAMA</i> <u>282</u> (19):1839-1844 (1999)
	AC-14	Updike et al., "The Enzyme Electrode," <i>Nature</i> <u>214</u> :956-958 (1967)
	AC-15	Wang, Joseph, "Permselective Coatings for Amperometric Biosensing," Chapter 10 in ACS Symposium Series No. 487 <i>American Chemical Society</i> (1992)
	AC-16	Welfle, Dr. K., et al., "Glucose Oxidase of <i>Penicillium notatum</i> . Purification, Stability and Hydrodynamic Properties," <i>Studia Biophysica</i> <u>138</u> (3):245-260 (1990).

Examiner: \_\_\_\_\_ Date Considered: \_\_\_\_\_

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.